

**FORM PTO-1449 (Modified)**

ATTY. DOCKET NO.

SERIAL NO

LIST OF PATENTS AND  
PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE  
STATEMENT

C1039/7020

09/337,584

APPLICANT Krieg

FILING DATE June 21, 1999

GROUP 1635

**U.S. PATENT DOCUMENTS**

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
* <i>h</i>		3,906,092	09/16/75	Hilleman et al.	424	209.1	
* <i>h</i>		5,248,670	09/28/93	Draper et al.	514	44	
* <i>h</i>		5,585,479	12/17/96	Hoke et al.	536	24.5	
* <i>h</i>		5,663,153	09/02/97	Hutcherson et al.	514	44	
* <i>h</i>		5,723,335	03/03/98	Hutcherson et al.	435	375	
* <i>h</i>		5,786,189	07/28/98	Locht et al.	435	172.3	
* <i>h</i>		5,849,719	12/15/98	Carson et al.	514	44	10/04/96

**FOREIGN PATENT DOCUMENTS**

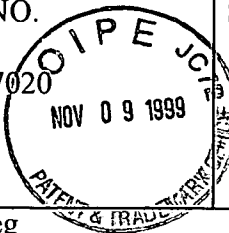
		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No	
* <i>h</i>		WO 91/12811	09/05/91	PCT <i>wo</i>	A61K	31/70		
* <i>h</i>		0468520 A3	01/29/92	EPØ	A61K	31/70		
* <i>h</i>		WO 92/03456	03/05/92	PCT <i>wo</i>	C07H	15/12		
* <i>h</i>		WO 92/18522	10/29/92	PCT <i>wo</i>	C07H	21/00		
* <i>h</i>		WO 92/21353	12/10/92	PCT <i>wo</i>	A61K	31/70		
* <i>h</i>		0302758-81 B1	03/16/94	EPØ	C12N	15/37		
* <i>h</i>		WO 94/19945	09/15/94	PCT <i>wo</i>	A01N	43/04		
* <i>h</i>		WO 95/05853	03/02/95	Regents of the University of CA <i>wo</i>	—	—		
* <i>h</i>		WO 95/26204	10/95 10/5/95	PCT <i>wo</i>	A61K	48/00		
* <i>h</i>		WO 96/02555	02/01/96	PCT <i>wo</i>	—	—		
* <i>h</i>		WO 96/35782	11/14/96	Applied Research Systems <i>wo</i>	—	—		
* <i>h</i>		WO 97/28259	08/07/97	PCT <i>wo</i>	C12N	15/00		
* <i>h</i>		WO 98/18810	05/07/98	PCT <i>wo</i>	C07H	21/00		
* <i>h</i>		WO 98/37919	09/03/98	PCT <i>wo</i>	A61K	49/00		
* <i>h</i>		WO 98/40100	09/17/98	PCT <i>wo</i>	A61K	39/39		
* <i>h</i>		WO 98/52581	11/26/98	PCT <i>wo</i>	A61K	35/00		
* <i>h</i>		WO 98/14210	04/09/98	PCT <i>wo</i>	A61K	39/35		

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

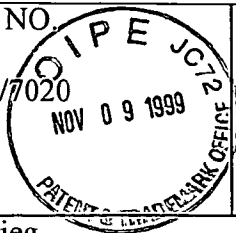
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<b>FORM PTO-1449 (Modified)</b>		<b>ATTY. DOCKET NO.</b>		<b>SERIAL NO</b>	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		C1039/7020		09/337,584	
					
		APPLICANT Krieg			
		FILING DATE June 21, 1999		GROUP 1635	
*	<i>h</i>	Adya N et al., Expansion of CREB's DNA recognition specificity by Tax results from interaction with Ala-Ala-Arg at positions 282-284 near the conserved DNA-binding domain of CREB. <i>Proc Natl Acad Sci USA</i> 91(12):5642-6, 7 Jun 1994.			
C1	<i>h</i>	Anderson, G., et al., "TH2 and 'TH2-like' cells in allergy and asthma: pharmacological perspectives", <i>TIPS</i> , 15:324-332, (1994)			
*	<i>h</i>	Angier, N., Microbe DNA Seen as Alien By Immune System, <i>New York Times</i> , 4/11/95			
*	<i>h</i>	Azad RF et al., Antiviral Activity of a Phosphorothioate Oligonucleotide Complementary to RNA of the Human Cytomegalovirus Major Immediate-Early Region. <i>Antimicrobial Agents and Chemotherapy</i> , 37:1945-1954, September, 1993.			
*	<i>h</i>	Azuma, Biochemical and Immunological Studies on Cellular Components of Tubercle Bacilli, <i>Kekkaku</i> , Vol. 69, 9:45-55, 1992.			
*	<i>h</i>	Ballas ZK et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 157(5):1840-5, 1996.			
*	<i>h</i>	Bayever, E., Systemic Administration of a Phosphorothioate Oligonucleotide with a Sequence Complementary to p53 for Acute Myelogenous leukemia and Myelodysplastic Syndrome: Initial Results of a Phase I Trial, <i>Antisense Res. &amp; Dev.</i> (1993), 3:383-390.			
*	<i>h</i>	Bennett RM et al., DNA binding to human leukocytes. Evidence for a receptor-mediated association, internalization, and degradation of DNA. <i>J Clin Invest</i> 76(6):2182-90, 1985.			
*		<del>Berg DJ et al., Interleukin-10 is a central regulator of the response to LPS in murine models of endotoxic shock and the Shwartzman reaction but not endotoxin tolerance. <i>J Clin Invest</i> 96(5):2339-47, 1995.</del>			
*		<del>Blanchard DK et al., Interferon-gamma induction by lipopolysaccharide: dependence on interleukin 2 and macrophages. <i>J Immunol</i> 136(3):963-70, 1986.</del>			
*	<i>h</i>	Blaxter et al., Genes expressed in <i>Brugia malayi</i> infective third stage larvae. <i>Molecular and Biochemical Parasitology</i> , 77:77-93. April 1996			
*	<i>h</i>	Boggs RT et al., Characterization and modulation of immune stimulation by modified oligonucleotides. <i>Antisense Nucleic Acid Drug Dev</i> 7(5):461-71, Oct 1997.			
*	<i>h</i>	Branda RF et al., Amplification of antibody production by phosphorothioate oligodeoxynucleotides. <i>J. Lab Clin Med</i> 128(3):329-38, Sep 1996.			
*	<i>h</i>	Branda et al., Immune Stimulation by an Antisense Oligomer Complementary to the rev gene of HIV-1. <i>Biochemical Pharmacology</i> , Vol. 45, 10:2037-2043, 1993.			
*	<i>h</i>	Briskin M et al., Lipopolysaccharide-unresponsive mutant pre-B-cell lines blocked in NF-kappa B activation. <i>Mol Cell Biol</i> 10(1):422-5, Jan 1990.			
*	<i>h</i>	Chace, J. et al., Regulation of Differentiation in CD5+ and Conventional B Cells, <i>Clinical Immunology and Immunopathology</i> , (1993), 68:3:327-332.			
*	<i>h</i>	Chang YN et al., The palindromic series I repeats in the simian cytomegalovirus major immediate-early promoter behave as both strong basal enhancers and cyclic AMP response elements. <i>J Virol</i> 64(1):264-77, Jan 1990.			
*	<i>h</i>	Chu RS et al., CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity. <i>J Exp Med</i> 186(10):1623-31, 17 Nov 1997.			
*	<i>h</i>	Cowdery JS et al., Bacterial DNA induces NK cells to produce IFN-gamma in vivo and increases the toxicity of lipopolysaccharides. <i>J Immunol</i> 156(12):4570-5, 15 Jun 1996.			
*	<i>h</i>	Crosby et al., The Early Responses Gene FGFI-C Encodes a Zinc Finger Transcriptional Activator and is a Member of the GCGGGGGCG (GSG) Element-Binding Protein Family. <i>Mol. Cell. Biol.</i> , 2:3835-3841, 1991.			
*	<i>h</i>	Crystal, Transfer of Genes to Humans: Early Lessons and Obstacles to Success. <i>Science</i> , Vol. 270, pp. 404-410, 1995.			

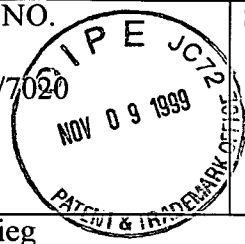
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*		D'Andrea A et al., Interleukin 10 (IL-10) inhibits human lymphocyte interferon-gamma production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells. <i>J Exp Med</i> 178(3):1041-8, 1993.	
*	✓	Englisch et al., Chemically Modified Oligonucleotides as Probes and Inhibitors, <i>Angew. Chem. Int. Ed. Engl.</i> , 30:613-629, 1991.	
*	✓	Erb KJ et al., Infection of mice with Mycobacterium bovis-Bacillus Calmette-Guerin (BCG) suppresses allergen-induced airway eosinophilia. <i>J Exp Med</i> 187(4):561-9, 16 Feb 1998.	
*	✓	Elinor, Carrier sequence selection - one key to successful vaccines, <i>Immunology Today</i> , Vol. 13, 2:52-55, 1992.	
*	✓	Fox RL, Mechanism of action of hydroxychloroquine as an antirheumatic drug. <i>Chemical Abstracts</i> , 120:15, Abstract No. 182630 (April 29, 1994).	
*	✓	Gura, T., Antisense Has Growing Pains. <i>Science</i> (1995), 270:575-576.	
*	✓	Hadden J et al., Immunostimulants. <i>TIPS</i> , (1993), 141:169-174.	
*	✓	Hadden J et al., Immunopharmacology, <i>JAMA</i> , (1992) 268:20:2964-2969.	
*	✓	Halpern MD et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 167(1):72-8, 1996.	
*	✓	Hatzfeld J., Release of Early Human Hematopoietic Progenitors from Quiescence by Antisense Transforming Growth Factor β1 or Rb Oligonucleotides, <i>J. Exp. Med.</i> , (1991) 174:925-929.	
*	✓	Highfield PE, Sepsis: the More, the Murkier. <i>Biotechnology</i> , 12:828, August 12, 1994.	
*	✓	Hoeffler JP et al., Identification of multiple nuclear factors that interact with cyclic adenosine 3',5'-monophosphate response element-binding protein and activating transcription factor-2 by protein-protein interactions. <i>Mol Endocrinol</i> 5(2):256-66, Feb 1991.	
*	✓	Iguchi-Ariga SM and Shaffner W, CpG methylation of the cAMP-responsive enhancer/promoter sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation. <i>Genes Dev</i> 3(5):612-9, May 1989.	
*	✓	Iverson, P., et al., "Pharmacokinetics of an Antisense Phosphorothioate Oligodeoxynucleotide against revere from Human Immunodeficiency Virus Type 1 in the Adult male Rats Following Single Injections and Continuous Infusion", <i>Antisense Research and Development</i> , (1994), 4:43-52	
*	✓	Ishikawa R et al., IFN induction and associated changes in splenic leukocyte distribution. <i>J Immunol</i> 150(9):3713-27, 1 May 1993	
*	✓	Jakway JP et al., Growth regulation of the B lymphoma cell line WEHI-231 by anti-immunoglobulin, lipopolysaccharide, and other bacterial products. <i>J Immunol</i> 137(7):2225-31, 1 Oct 1986.	
*	✓	Jaroszewski JW and Cohen JS, Cellular uptake of antisense oligonucleotides. <i>Adv Drug Delivery Rev</i> 6(3):235-50, 1991.	
C2	✓	Kawano, K., et al., "Analysis and Regulation of interferon-gamma production by peripheral blood lymphocytes from patients with bronchial asthma", ABSTRACT, <i>Arerugi</i> , 43:3:482-91, (1994)	
*	✓	Kimura Y et al., Binding of Oligoguanylate to Scavenger Receptors Is Required for Oligonucleotides to Augment NK Cell Activity and Induce IFN, <i>J. Biochem.</i> , Vol. 116, 5:991-994, 1994.	
*	✓	Kline JN et al., CpG motif oligonucleotides are effective in prevention of eosinophilic inflammation in a murine model of asthma. <i>J Invest Med</i> 44(7):380A, 1996.	
*	✓	Kline JN et al., Immune redirection by CpG oligonucleotides. Conversion of a Th2 response to a Th1 response in a murine model of asthma. <i>J Invest Med</i> 45(3):282A, 1997.	
*	✓	Kline JN et al., CpG oligonucleotides can reverse as well as prevent Th2-mediated inflammation in a murine model of asthma. <i>J Invest Med</i> 45(7):298A, 1997.	

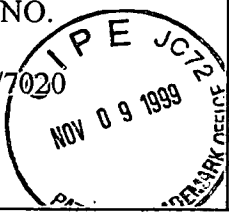
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*	✓	Klinman DM et al., CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. <i>Proc Natl Acad Sci USA</i> 93(7):2879-83, 1996.			
*	✓	Krieg AM, An innate immune defense mechanism based on the recognition of CpG motifs in microbial DNA. <i>J Lab Clin Med</i> 128(2):128-33, 1996.			
*	✓	Krieg AM et al., Uptake of oligodeoxyribonucleotides by lymphoid cells is heterogeneous and inducible. <i>Antisense Res Dev</i> 1(2):161-71, Summer 1991.			
*	✓	Krieg AM et al., Oligodeoxynucleotide modifications determine the magnitude of B cell stimulation by CpG motifs. <i>Antisense Nucleic Acid Drug Dev</i> 6(2):133-9, Summer 1996.			
*	✓	Krieg AM et al., "Modification of antisense phosphodiester oligodeoxynucleotides by a 5' cholesteryl moiety increases cellular association and improves efficacy", <i>Proc. Natl. Acad. Sci.</i> , (1993), 90:1048-1052			
*	✓	Krieg AM et al., "CpG DNA: A Pathogenic Factor in Systemic Lupus Erythematosus?", <i>Journal of Clinical Immunology</i> , (1995) 15:6:284-292			
*	✓	Krieg AM et al, "Phosphorothioate Oligodeoxynucleotides: Antisense or Anti-Protein?", <i>Antisense Research and Development</i> , (1995), 5:241			
*	✓	Krieg AM et al., "Leukocyte Stimulation by Oligodeoxynucleotides", <i>Applied Antisense Oligonucleotide Technology</i> , (1998), 431-448			
*	✓	Krieg AM et al., CpG motifs in bacterial DNA trigger direct B-cell activation. <i>Nature</i> 374:546-9, 1995.			
*	✓	Krieg AM et al, "The role of CpG dinucleotides in DNA vaccines", <i>Trends in Microbiology</i> , Vol. 6, pp. 23-27, Jan 1998.			
*	✓	Krieg AM et al, "A Role for Endogenous Retroviral Sequences in the Regulation of Lymphocyte Activation, the <i>Journal of Immunology</i> , Vol. 143, 2448-2451, Oct. 1989			
*	✓	Kuramoto et al., Oligonucleotide Sequences Required for Natural Killer Cell Activation, <i>Jpn. J. Cancer Res.</i> , 83:1128-1131, November 1992.			
*	✓	Leonard et al., Conformation of Guanine 8-Oxoadenine Base Pairs in the Crystal Structure of d(CGCGAATT(08A)GCG). <i>Biochemistry</i> , 31(36):8415-8420, 1992.			
*	✓	Macfarlane DE and Manzel L, Antagonism of immunostimulatory CpG-oligodeoxynucleotides by quinacrine, chloroquine, and structurally related compounds. <i>J Immunol</i> 160(3):1122-31, Feb 1.1998.			
*	✓	Mastrangelo et al. <i>Seminars in Oncology</i> . Vol. 23, 1:4-21, 1996.			
*	✓	Matson S and Krieg AM, Nonspecific suppression of [3H]thymidine incorporation by "control" oligonucleotides. <i>Antisense Res Dev</i> 2(4):325-30, Winter 1992.			
*	✓	McIntyre KW et al., A sense phosphorothioate oligonucleotide directed to the initiation codon of transcription factor NF-kappa B p65 causes sequence-specific immune stimulation. <i>Antisense Res Dev</i> 3(4):309-22, Winter 1993.			
*	✓	Messina et al., The Influence of DNA Structure on the <i>in vitro</i> Stimulation of Murine Lymphocytes by Natural and Synthetic Polynucleotide Antigens. <i>Cellular Immunology</i> , 147:148-157, 1993.			
*	✓	Messina et al., Stimulation of <i>in vitro</i> Murine Lymphocyte Proliferation by Bacterial DNA. <i>J. Immunol.</i> , Vol. 147, 6:1759-1764, September 15, 1991.			
*	✓	Mojcik, C., et al., "Administration of a Phosphorothioate Oligonucleotide Antisense Murine Endogenous Retroviral MCF env Causes Immune Effect in vivo in a Sequence-Specific Manner", <i>Clinical Immunology and Immunopathology</i> , (1993), 67:2:130-136			
*	✓	Mottram et al., A novel CDC2-related protein kinase from leishmania mexicana LmmCRK1 is post-translationally regulated during the life cycle. <i>J. Biol. Chem.</i> 268:28, 21044-21052 (October 1993).			
*	✓	New England BIOLABS 1988-1989 Catalog, item # 1230			

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*[Signature]* 7/27/01

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*	<i>h</i>	Nyce JW and Metzger WJ, DNA antisense therapy for asthma in an animal model. <i>Nature</i> 385:721-725, 20 Feb 1997.			
*	<i>h</i>	Pisetsky, D., "Stimulation of in vitro proliferation of murine lymphocytes by synthetic oligodeoxynucleotides", <i>Molecular Biology Repairs</i> , (1993) 18:217-221			
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*	<i>h</i>	Pisetsky, The Immunological Properties of DNA, <i>The Journal of Immunology</i> , pp. 421-423 (1996).			
*	<i>h</i>	Pisetsky, Immunological Consequences of Nucleic Acid Therapy, <i>Antisense Research and Development</i> , 5:219-225 (1995).			
*	<i>h</i>	Raz E et al., Preferential induction of a Th1 immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization. <i>Proc Natl Acad Sci USA</i> 93(10):5141-5, 14 May 1996.			
C3	<i>h</i>	Ricci, M., et al., "T cells, cytokines, IgE and allergic airways inflammation", <i>J Invest Allergol Clin Immunol</i> , 4:5:214-220, (1994)			
*	<i>h</i>	Roman M et al., Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants. <i>Nat Med</i> 3(8):849-54, Aug 1997.			
*	<i>h</i>	Sato et al., Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization, <i>Science</i> , Vol. 273, pp. 352-354, 1996.			
*	<i>h</i>	Schnell et al., Identification and characterization of a <i>Saccharomyces cerevisiae</i> gene (PARI) conferring resistance to iron chelators. <i>Eur. J. Biochem.</i> , 200:487-493. Sept. 1991			
*		Schwartz DA et al., Endotoxin responsiveness and grain dust induced inflammation in the lower respiratory tract. <i>Am J Physiol</i> 267(5 Pt 1):L609-17, 1994.			
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*	<i>h</i>	Schwartz DA et al., CpG motifs in bacterial DNA cause inflammation in the lower respiratory tract. <i>J Clin Invest</i> 100(1):68-73, 1 Jul 1997.			
*	<i>h</i>	Shirakawa T et al., The inverse association between tuberculin responses and atopic disorder. <i>Science</i> 275(5296):77-9, 3 Jan 1997.			
C4	<i>h</i>	Spiegelberg, H., et al., "Recognition of T Cell Epitopes and Lymphokine Secretion by Rye Grass Allergen <i>Lolium perenne</i> I-Specific Human T Cell Clones", <i>J of Immunology</i> , 4706-4711, (1994)			
*	<i>h</i>	Sparwasser T et al., Macrophages sense pathogens via DNA motifs: induction of tumor necrosis factor-alpha-mediated shock. <i>Eur J Immunol</i> 27(7):1671-9, Jul 1997.			
*	<i>h</i>	Stein CA et al., Oligonucleotides as inhibitors of gene expression: a review. <i>Cancer Research</i> , 48:2659-2668, 1988.			
*	<i>h</i>	Stull et al., Antigene, Ribozyme, and Aptamer Nucleic Acid Drugs: Progress and Prospects, <i>Pharmaceutical Res.</i> , Vol. 12, 4:465-483, 1995.			
*	<i>h</i>	Subramanian et al., Theoretical Considerations on the "Spine of Hydration" in the Minor Groove of d(CGCGAATTCGCG) d(GCGCTTAAGCGC): Monte Carlo Computer Simulation. <i>Proc. Nat'l. Acad. Sci. USA</i> , 85:1836-1840, 1988.			
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*		<del>Thorne PS., Experimental grain dust atmospheres generated by wet and dry aerosolization techniques. <i>Am J Ind Med</i> 25(1):109-12, 1994.</del>			
*	<i>h</i>	Tokunaga T et al., Synthetic Oligonucleotides with Particular Base Sequences form the cDNA Encoding Proteins of <i>Mycobacterium bovis</i> BCG Induce Interferons and Activate Natural Killer Cells, <i>Microbiol. Immunol.</i> , Vol. 36, 1:55-66, 1992.			

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*	<i>h</i>	Tokunaga et al., A Synthetic Single-Stranded DNA, Ply (dG, dC), Induces Interferon $\alpha/\beta$ and $-\gamma$ , Augments Natural Killer Activity and Suppresses Tumor Growth. <i>Jpn. J. Cancer Res.</i> , 79:682-686, June 1988.			
*	<i>h</i>	Uhlmann et al., Antisense Oligonucleotides: A New Therapeutic Principle. <i>Chemical Reviews</i> , 90:543-584, 1990.			
*	<i>h</i>	Wagner RW, Gene inhibition using antisense oligodeoxynucleotides. <i>Nature</i> , 372:L333-335, 1994.			
C5	<i>h</i> /	<b>Walker, C., et al., "Activated T Cells and Cytokines in Bronchoalveolar Lavages from Patients with Various Lung Diseases Associated with Eosinophilia", <i>Am J Respir Crit Care Med</i>, 150:1038-1048, (1994)</b>			
*	<i>h</i>	Wallace et al., Oligonucleotide probes for the screening of recombinant DNA libraries. <i>Methods in Enzymology</i> , 152:432-442 (1987).			
*	<i>h</i>	Weiss R., Upping the Antisense Ante: Scientists bet on profits from reverse genetics. <i>Science</i> , 139:108-109, 1991.			
*	<i>h</i>	Whalen R, DNA Vaccines for Emerging Infection Diseases: What If?, <i>Emerging Infectious Disease</i> , Vol. 2, 3:168-175, 1996.			
*	<i>h</i>	Wu GY et al., Receptor-mediated gene delivery and expression in vivo. <i>J. Biol. Chem.</i> , 263:14621-14624, 1988.			
*	<i>h</i>	Wu-Pong S., Oligonucleotides: Opportunities for Drug Therapy and Research. <i>Pharmaceutical Technology</i> , 18:102-114, 1994.			
*	<i>h</i>	Yamamoto S et al., DNA from bacteria, but not from vertebrates, induces interferons, activates natural killer cells and inhibits tumor growth. <i>Microbiol Immunol</i> 36(9):983-97, 1992.			
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\* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 08/738,652, filed October 30, 1996, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

*[Signature]*

7/27/01

SER. No. 09/337,584

EXAMINER <i>A. Hall</i>	DATE CONSIDERED 7/27/01
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

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